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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,837	06/25/2001	Anand V. Gumaste	MICRODOSE 00.01	9414

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EXAMINER

PATEL, NIHIL B

ART UNIT	PAPER NUMBER
3743	8

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/888,837	GUMASTE, ANAND V.
	Examiner Nihir Patel	Art Unit 3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) 4-7 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3 and 8-15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Response to Arguments

1. In response to applicant's argument that "the blister pack is designed for mating with a vibratory de-aggregator whereby the blister pack contents will be forcibly ejected from the pack, i.e. by the vibratory de-aggregator", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art.

See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant's arguments filed on October 15, 2002 have been fully considered but they are not persuasive. The applicant states that Eisele et al. nowhere teaches or suggests frangible overlying spaced top crowned areas 54 (see figure 5) located over the first element 56 (see figure 5) spaced areas (see figures 2, 3, and 4 the area located between the bumps 36).

Response to Amendment

2. Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6. Claim 5 states that the first element includes a depression opposite the top crowned areas. The first (bottom) element of figure 2 (elected species) does not include a depression opposite the top crowned areas.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Eisele et al. U.S. Patent No. 6,029,663. Referring to claim 1, Eisele discloses a dry powder inhaler delivery system that comprises a first element 56 (see figure 5) having spaced area (see figures 2, 3, and 4 the area located between the bumps 36) and a frangible second element 54 (see figure 5) overlying the first element 56 (see figure 5) and defining a plurality of spaced top crowned areas (see figure 2-5) located over the first element (see figure 5) spaced areas (see figure 2, 3, and 4 the area located between the bumps 36), and containing powder 62 (see figure 5) or liquid material.

In response to applicant's argument that "for interfacing and coupling with the inhaler vibratory de-aggregator", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Referring to claim 8, Eisele shows that the material comprises a medication. Refer to figure 5 and column 3 lines 10 through 20.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Eisele et al. U.S. Patent No. 5,921,237.

Eisele discloses the applicant's invention as claimed with the exception of providing a top crowned areas that are shaped as inverted cones.

Eisele discloses a dry powder inhaler that does provide a top crowned areas that are shaped as inverted cones (see figure 22 and col.3 lines 60-67). Therefore it would be obvious to modify Eisele's invention by providing a top crowned areas that are shaped as inverted cones in order save space in the blister pack.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Pera U.S. Patent No. 5,944,012.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a vitamin.

Pera discloses a method for dispensing antioxidant vitamin by inhalation background of the invention that does state that the material comprises a vitamin (col. 8 lines 1-10). Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a vitamin so that one knows the limitations of the invention.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Hendricks U.S. Patent No. 5,699,789.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a hormone or a steroid.

Hendricks discloses a dry powder inhaler that does state that the material comprises a hormone or a steroid (col. 6 lines 46-55). Therefore it would be obvious to modify Eisele's

invention by stating that the material comprises a hormone or a steroid so that one knows the limitations of the invention.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Shyjan U.S. Patent No. 6,312,909.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a bioactive material.

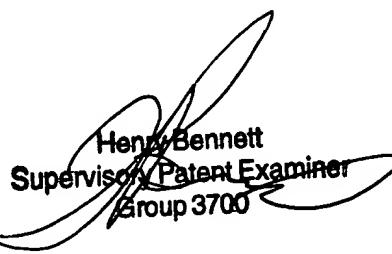
Shyjan discloses a compositions and methods for the diagnosis prevention and treatment of tumor progression that does state that the material comprises a bioactive material. Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a bioactive material so that one knows the limitations of the invention.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP
December 12, 2002


Henry Bennett
Supervisory Patent Examiner
Group 3700